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| APPLICATION NO.                               | FILING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|--|----------------------|---------------------|------------------|
| 10/670,907                                    | 09/25/2003   | Gisele Veilleux      | GOUD:037US          | 6020             |
|   | 32425 7590 06/15/2007<br>FULBRIGHT & JAWORSKI L.L.P. |                      | EXAMINER            |                  |
| 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701 |  |                      | CHOI, FRANK I       |                  |
|   |  |                      | ART UNIT            | PAPER NUMBER     |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action Before the Filing of an Appeal Brief

| Application No. |            | Applicant(s)    |  |
|-----------------|------------|-----------------|--|
|                 | 10/670,907 | VEILLEUX ET AL. |  |
|                 | Examiner   | Art Unit        |  |
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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 15 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires \_\_\_\_\_months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). **NOTICE OF APPEAL** 2. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: Claim(s) withdrawn from consideration: \_\_\_\_\_. AFFIDAVIT OR OTHER EVIDENCE 8. 🔲 The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and

- was not earlier presented. See 37 CFR 1.116(e).
- 9. 

  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
- 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

## REQUEST FOR RECONSIDERATION/OTHER

- 11. Mathematical The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
- 12. Mote the attached Information Disclosure Statement(s). (PTO/SB/Q8) Paper No(s).

13. Other:

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Continuation of 11. does NOT place the application in condition for allowance because: The Examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons of record setforth in the prior Office Action (12/15/2006) and the further reasons below. The Applicant argues that there is sufficient written support for the term "distinct mean particle sizes", however, none of the disclosure cited recites said limitation. See In re Ruschig, 154 USPQ 118, 123 (CCPA 1967) (the court held that the fact that it may be easy enough to imagine the claimed compound from the disclosure of the Specification, the problem is that there is no such disclosure). As such, the 35 USC 112, 1st paragraph rejection is maintained. With respect to the 103 rejection, the Supreme Court holding in KSR International v. Teleflex, Inc., 82 USPQ2d 1385 (US 2007) must be considered. The Applicant argues that Chen and Chu et al. are focused on different technical problems. However, as held by the Supreme Court in KSR, any need or problem known in the field of endeavor at the time of the inventions and addresed by the prior art can provide a reason for combining the elements in the manner claimed. Further, it is error to assume that one of ordinary skill in the art would only be led to those elements of prior art designed to solve the same problem. The claims do not define the term "distinct mean particle sizes". Chen et al. and Chu et al. both disclose that roller compaction methods are well known in the art. Further, Chen et al. discloses that the granules can be sieved to select granules of particular mesh size. Since the term "distinct mean particles sizes" is not defined by the claims or the Specification, the Applicant has not provided sufficient evidence to establish that the prior art does not make the claimed invention obvious. The Applicant cites to Gillette v. S.C. Johnson & Son for the premise that "obvious to try" is not a standard for obviousness. However, the Supreme Court in KSR held that it is error to conclude that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". In any case, the Examiner has provided a reasoning to modify and/or combine the references as set forth in the prior Office Action (12/15/2006) at page 4. The Applicant argues that the prior art does not disclose the use of more than one active ingredient. However, as held by the Supreme Court in KSR, one of ordinary skill in the art is not an automaton. Compaction and sieving to the desired mesh size is disclosed as well as the combination of active ingredients. As such, where it is desired to use more than one active ingredient, i.e. in a combination, it would have been well within the skill of one ordinary skill in the art to process both active ingredients as the same time to avoid having to spend the time to go through the process separately for each active ingredient. The Applicant argues that it has provided surprising and unexpected results, however, any said results must be commensurate with the scope of the claims. As indicated indicated in the prior Office Action (12/15/2006) the evidence of superior properties in one species is insufficient to establish the non-obviousness of a subgenus containing hundreds of compounds. The citation to paragrph [0004] as indicated above and in the prior Office Action (12/15/2006) does not support the limitation "dsitinct mean particles sizes" as such, the evidence does not show unexpected properties of the claimed invention. Even if the same did show unexpected properties, the same is not sufficient to overcome the prior art as the evidence amounts to nothing more than to verification testing to optimize selection of known granulate processing methods. See Pfizer Inc. v. Apotex Inc., 82 USPQ2d 1321, 1338 (Fed Cir. 2007) (creating a process that is more desirable for example because it is more efficient is universal, and even common sensical).